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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,066	11/07/2001	Scott L. Diamond	3936-011568	3883

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EXAMINER

LAM, ANN Y

ART UNIT PAPER NUMBER

1641

DATE MAILED: 03/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/036,066	<b>Applicant(s)</b> DIAMOND, SCOTT L.	
	<b>Examiner</b> Ann Y. Lam	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 10-15 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 and 16-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 16, 2006 has been entered.

Claims 1-9 and 16-18 have been withdrawn. Claims 10-15 are examined below.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10, line 2, recites "a set of operating instructions resident in computer software". Claim 10, line 7, also recites an "operating software". It is also not clear if the "computer software" in line 2 of claim 10 is the same as the "operating software" as

in line 6 of claim 10. For examination purposes the Office will interpret them to be different.

It is also not clear in claim 10, line 2, whether the operating instructions are in (or operatively connected to) the dot applicators of line 3 or the device for aerosol generation in line 4. For purposes of examination, the Office will interpret the computer software in line 2 to be connected to the device for aerosol generation.

Claim 10, line 6, recites "a computer-controlled xy positioner". It is not clear whether the xy positioner is in (or operatively connected to) the dot applicators in line 3 or to the device for aerosol generation in line 4. For purposes of examination, the Office will interpret the xy positioner to be connected to the dot applicators.

Also, it is not clear whether the xy positioner in claim 10, line 6, is referring to the same xy positioner system as in claim 12, line 6.

Claim 10, line 7, recites "a computer and operating software". It is not clear whether the computer and operating software is in (or operatively connected to) the dot applicators in line 3 or the device for aerosol generation in line 4 or to both. The Office will interpret them to be connected to the dot applicators. Also, if Applicant intends for the computer and software to reside in or is operatively connected to only one of the device then it is also not clear if a computer is being claimed for the other device (since both the dot applicator and the aerosol generation device are recited as being "computer-controlled.")

Claim 10, line 8, recites "a chamber for control of biological samples". It is not clear whether the chamber is in or operatively connected to the dot applicators in line 3

or the device for aerosol generation in line 4. Although it appears that the chamber is in or connected to the device for aerosol generation, it is not clear. The Office will interpret for examination purposes the chamber to be in the aerosol device.

Claim 10, line 4, recites “a second, separate computer-controlled device for biological sample aerosol generation”. However this language appears to imply that there is a first set of separate computer-controlled device for biological sample aerosol generation, even though a first set is never claimed. (It appears that Applicant merely intends to distinguish the aerosol generation device from the “first set of computer-controlled reactant dot applicators” in line 3. However, Applicant should distinguish them in another way that is clear).

Claim 10, lines 10-11, recites “the aerosolized biological sample droplets”. The claim lacks antecedent basis for this limitation. (Applicant should just take out the word “the” to overcome this rejection.)

Claim 11, lines 1-2, recites “wherein said system contains one or more subcomponents”. It is not clear whether or not the system *further comprises* one or more subcomponents (in addition to the dot applicators or aerosol generation device in claim 10), or whether the dot applicators comprises the one or more subcomponents, or whether the aerosol generation device comprises the one or more subcomponents. (Thus it is also not clear in claim 12, which depends from claim 11, whether the apparatuses in the Markush group are referring to subcomponents of the dot applicators or the aerosol generation device.) The Office will interpret the claim to mean that the

Art Unit: 1641

subcomponents are part of the aerosol generation device because this appears to be the case according to Applicant's specification.

Claim 12, line 6, recites "gas flow meter/controller". It is not clear whether Applicant intends –gas flow meter and controller—or –gas flow meter or controller--.

Claim 12, line 6, recites "exhaust/filtration fan". It is not clear whether Applicant intends –exhaust and filtration fan—or exhaust or filtration fan--.

Claim 13, recites "said microsyringes" in line 1. The claim lacks antecedent basis for this limitation.

Claim 14, recites "said microsyringes" in line 1. The claim lacks antecedent basis for this limitation.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henderson et al., 6,573,369, in view of Eipel et al., 6,737,024, and further in view of Church, 6,432,360, and Engle et al., 6,521,325.

Henderson et al. disclose the invention substantially as claimed. More specifically, Henderson et al. disclose an assay system comprising :

a first set of computer-controlled reactant dot applicators (AFM, col. 12, line 33);

a computer-controlled xy positioner (i.e., deposition instrument, col. 9, line 49);

a computer and operating software (col. 9, lines 51-52 and col. 12, lines 33-36); and

The Office notes that Henderson et al. teach that the AFM device can deposit as little as a single macromolecule (col. 13 lines 19-20) and that the center of one molecular domain to the center of the next domain may be as small or smaller than one micron (col. 13, lines 41-44). The AFM can produce an array on a substrate (col. 13, lines 19-25). Henderson et al. teach that the array may be utilized on site or shipped to another location for exposure of the array to a sample medium (col. 13, lines 22-27). Henderson et al. also teach that in use, the array may for example be dipped in a solution or exposed to a gas to expose the array to a medium (col. 14, lines 33-34). However, Henderson et al. do not teach that the array may be exposed to a sample medium using an aerosol generation device as claimed by Applicant.

More specifically, Henderson et al. do not teach a computer-controlled aerosol generation device (nor a chamber for control of biological samples, which the Office interprets to be in the aerosol generation device) wherein the first set of computer-controlled reactant dot applicators are capable of creating a plurality of reaction spots to

Art Unit: 1641

which the aerosolized biological sample droplets are applied simultaneously by said second, separate computer-controlled device for sample aerosol generation for computer-enhanced assay of any reaction between the sample droplets and the dot constituents. However, Eipel et al. in view of Church teaches such an aerosol generation device.

Eipel et al. teach that ink jet printers may be used to apply sample material and reagents to a support (col. 4, lines 32-40). Moreover, Church teach that a printer that is more broadly focused may spray an entire support at once (col. 27, lines 5, 16-17, and 30-35). It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a printer as taught by Eipel et al. with the Henderson array because Eipel et al. teach that a printer may be used to apply sample materials and reagents to a support, such as the Henderson support containing an array. Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a printer that is more broadly focused because Church teaches that such a printer may be used to spray an entire support at once. In any case, the Eipel et al. printer by itself is capable of applying droplets simultaneously to the reactant spots of the Henderson et al. device because a printer such as that disclosed by Eipel et al. ejects more than one molecule and the Henderson et al. device can place as little as a single molecule on each domain and that the domains can be smaller than one micron apart.

The Office notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in



Art Unit: 1641

order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, the prior art structure is capable of performing the intended use. In this case, the Eipel et al. device, by itself, or in view of Church, is capable of applying droplets simultaneously to the reactant spots as described above.

The above references also do not teach clearly that the printer is computer-controlled, nor do they clearly teach a set of operating instructions in a computer software as claimed in line 2 (which is interpreted by the Office to be for controlling the device for aerosol generation). Engle et al. teach these limitations.

Engle et al. teach that a computer, software and printer will control the size, number and placement of the drops (col. 2, lines 23-24), which may be biological fluids or chemical assay reagents (see abstract, second sentence). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a computer and software as taught by Engle et al. for the Eipel et al. printer because Engle et al. teach that a computer and software can control the size, number and placement of drops, as would be desirable for convenience.

As to claims 11 and 12, the claimed system contains a subcomponent (i.e., ink-jet printer, see Eipel et al., col. 4, lines 32-40.)

2. Claims 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henderson et al., 6,573,369, in view of Tisone, 5,738,728, and further in view of Church, 6,432,360.

Henderson et al. disclose the invention substantially as claimed. More specifically, as to claim 10, Henderson et al. disclose an assay system comprising :

- a first set of computer-controlled reactant dot applicators (AFM, col. 12, line 33);

- a computer-controlled xy positioner (i.e., deposition instrument, col. 9, line 49);

- a computer and operating software (col. 9, lines 51-52 and col. 12, lines 33-36); and

- a chamber (col. 11, lines 60-62, disclosing the immersion of the tip of the probe device in a solution; the element containing the solution is considered the claimed chamber) for control of biological samples.

The Office notes that Henderson et al. teach that the AFM device can deposit as little as a single macromolecule and that the AFM can produce an array on a substrate (col. 13, lines 19-25). Henderson et al. teach that the array may be utilized on site or shipped to another location for exposure of the array to a sample medium (col. 13, lines 22-27). Henderson et al. also teach that the array may be dipped in a solution or exposed to a gas (col. 14, lines 33-34). However, Henderson et al. do not teach that the array may be exposed to a sample medium using an aerosol generation device as claimed by Applicant.

More specifically, Henderson et al. do not teach a computer-controlled aerosol generation device wherein the first set of computer-controlled reactant dot applicators are capable of creating a plurality of reaction spots to which the aerosolized biological sample droplets are applied simultaneously by said second, separate computer-controlled device for sample aerosol generation for computer-enhanced assay of any reaction between the sample droplets and the dot constituents. However, Tisone in view of Church teaches such an aerosol generation device.

Tisone teaches a plurality of syringe pumps mounted on an apparatus for aerosolizing reagents onto a support (col. 3, lines 15-28, and col. 5, lines 55-59, and col. 8, lines 24-25) in a controlled and exacting manner (col. 3, lines 21). (The syringe pump taught by Tisone is considered to be a microsyringe pump, as claimed by Applicant, because it is small, see col. 5, lines 65-66.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a syringe pump as taught by Tisone with the Henderson array because Tisone teaches that syringe pumps may be used to apply sample materials and reagents to a support, such as the Henderson support containing an array, in a controlled and exacting manner. Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a spray device that is more broadly focused because Church teaches that such a spray device may be used to spray an entire support at once. In any case, the Eipel et al. printer by itself is capable of applying droplets simultaneously to the reactant spots of the Henderson et al. device because a printer such as that disclosed by Eipel et al. ejects

Art Unit: 1641

more than one molecule and the Henderson et al. device can place as little as a single molecule on each domain and that the domains can be smaller than one micron apart.

The Office notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, the prior art structure is capable of performing the intended use. In this case, the Tisone device, by itself, or in view of Church, is capable of applying droplets simultaneously to the reactant spots as described above.

Moreover, Tisone teaches a set of operating instructions resident in computer software (as claimed in claim 10, line 2) and that the aerosol generation device is computer controlled. That is, Tisone teaches that the dispensing apparatus may be integrated to an X-Y platform to coordinate delivery of the reagent (col. 7, lines 44-48). A microprocessor controls the platform and syringe pump (col. 7, lines 54-57). As to claims 11 and 12, the claimed subcomponent is the X-Y platform (i.e., the claimed xy positioner system in claim 12, line 6).

As to claim 13, the microsyringe pumps disclosed by Tisone are considered the claimed microsyringes. The microsyringes are capable of holding 1 microliter of biological sample (col. 7, line 51.)

As to claim 14, the microsyringes are capable of delivering samples at a constant flow rate (and col. 6, lines 38-42; and col. 7, lines 53-57.)

3. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Henderson et al., 6,573,369, in view of Tisone, 5,738,728, and Church, 6,432,360, as applied to claim 10 above, and further in view of French et al., 5,345,079.

Henderson et al. in view of Tisone and Church disclose the invention substantially as claimed (see claim 10 above), except for the device for aerosol generation being an ultrasonic nebulizer. French et al. teach this limitation.

French et al. teach that a device for analysis of a sample utilizing a droplet source that can be a micro pump or any form of conventional nebulizer, such as a spray nebulizer, or ultrasonic nebulizer (col. 17, lines 3-6.) It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute an ultrasonic nebulizer as taught by French et al. for the Tisone spraying device because French et al. teach that ultrasonic nebulizers are functional equivalents of spraying devices, such as the Tisone spraying device, for applying a material to a substrate for analysis.

### ***Response to Arguments***

Applicant's arguments filed February 16, 2006 have been considered but are moot in view of the new grounds of rejection. (Applicant argues that Tisone and French disclose a single apparatus whereas the newly amended claims require two separate devices. Two separate devices are described above in the new grounds of rejection.)


**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ann Lam



5/12/06